K041334

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EXHIBIT 2

510(k) Summary

Breathalyzer.net
A Division of KHN Solutions LLC
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San Francisco, CA 94133
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Fax: 415 693-0215
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May 14, 2004

Contact: Keith Nothacker, President

1. **Identification of the Device:**
   Proprietary-Trade Name: AlcoMate CA2000 Digital Alcohol Detector
   Classification Name: Device, breath trapping, alcohol, DJZ
   Common/Usual Name: Breath-alcohol test system

2. **Equivalent legally marketed devices** This product is similar in function to the Pre-amendments device: . Alco-Sensor (Intoximeters, Inc. St. Louis, MO)

3. **Indications for Use (intended use)** : The device is intended to measure alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.

4. **Description of the Device:** The AlcoMate is designed to measure deep lung air to test for the presence of alcohol in the blood. The relationship between alcohol in the blood and alcohol in the deep lung breath is well established by Henry's law in ratio of 2100:1 The AlcoMate is a D.O.T. approved alcohol screening device and uses a blow time of 5 seconds to capture an accurate deep lung sample. The AlcoMate contains a semiconductor oxide sensor designed to test for the presence of alcohol. The AlcoMate semiconductor contains a recently developed ceramic catalytic filter which greatly increases the sensors specificity to alcohol . The AlcoMate sensor uses oxide which has n-type conductivity when exposed to the atmosphere. This exposure causes a decrease in the number of electrons effecting absorbed oxygen molecules and thus increases resistance. If a specific gas (reducing gas) is presented, a reaction occurs with the absorbed oxygen which causes an increase in the electrons in the oxide molecules causing

a decrease in resistance. This change in resistance can be measured and used to identify a specific gas (such as alcohol) and can be quantified into a % concentration.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench, DOT, and user testing indicates that the new device is as safe and effective as the predicate device.

6. **Substantial Equivalence Chart**

Feature	**Alco-Sensor (Pre-Amendments Device)**	**AlcoMate CA2000**
INDICATION OF USE	The device is intended to measure alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.	SAME
MODE	Breath Alcohol Concentration	SAME
PRACTITIONER USE	Over the Counter	SAME
DISPLAY	2 Digit LED	3 Digit LED
POWER SOURCE	9 Volt Alkaline Battery	SAME, or auto cigar lighter (Optional)
BATTERY LIFE	300 Tests	SAME
Measurement Range	.00-.40%	SAME
Accuracy	+/-0.01%	SAME
TYPE OF SENSOR	Fuel cell sensor	Semiconductor-Oxide Sensor
ANATOMICAL SITE	Mouth	SAME
Mouthpiece	Replaceable	SAME
Warm Up Time	None	20 Seconds
DOT Approval	(Alco-Sensor III)	YES
Construction	Plastic case with internal circuit board	SAME
SIZE	5" x 3 ½"	5" x 3 ¼"
WEIGHT	171 grams.	200 grams

7. **Conclusion**

After analyzing bench tests, a risk analysis, electrical safety, EMC, DOT testing and user testing data, it is the conclusion of Breathalyzer.net that the AlcoMate CA2000 is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

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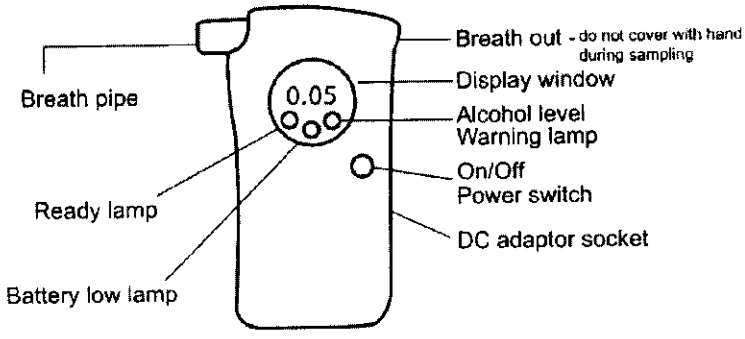
Digital Alcohol Detector

AlcoMate Model CA 2000

The CA2000 is intended to measure alcohol in human breath. Readings obtained by this device are used in the diagnosis of alcohol intoxication. The accuracy of this device has been established at a Blood Alcohol Concentration of 0.008 and 0.032. Accuracy at a Blood Alcohol Concentration greater than 0.032 has not been evaluated.

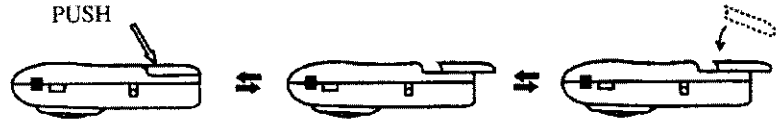
Part names



FINAL

Preparation

1. Install the 9 Volt Battery, supplied.



2. The tester comes with one plastic mouthpiece already over the breath pipe. You may wish to replace the mouthpiece for use by another person for sanitary reasons. To change mouthpieces, align the slot in the mouthpiece with the slot on the breath pipe.

Operation: Read these instructions before consuming alcohol.

WAIT! 20 minutes after drinking alcohol before taking a reading. If you don't wait, the reading will measure alcohol in the mouth, which does not accurately show your blood alcohol level.

1. Press the ON/OFF Power switch. WAIT! The detector will start to countdown from 200 to 000 on the display window. This warm up process prepares the sensor and circuit for testing. When you hear a BEEP and the green READY light comes on, go to step 2.

2. Take a deep breath, then blow steadily and continuously (at least 5 seconds) into the pipe until you hear another BEEP. Your lips should be sealed around the mouthpiece while blowing. Be careful not to cover the Breath out opening on the unit. (If you don't blow within 30 seconds, the unit automatically displays "OFF" and will turn off.) After the red and green display lights blink for 4 seconds, the test result will be displayed for 15 seconds. This is your Blood Alcohol Concentration, or BAC. Finally, the unit shows "OFF" for turn-off, along the BEEP sound. Press the ON/Off power switch to turn unit off.

If your blood alcohol concentration is:

Below 0.01%	0.01 to 0.04%	0.05% or Over	0.40% or Over
If you drank very little alcohol, your actual concentration may be below 0.01 %, and the reading may not be activated. However, the display shows 0.00% and you're in the safe range.	The reading will be displayed.	The Red WARN LED will flash along with a "BEEP" sound. Your ability to drive may be impaired. Don't drink and drive!	Display will read "Hot" and the Red WARN LED will flash along with "BEEP" sound.

For subsequent testing, repeat steps 1-2. Space tests at least 2 minutes apart.

Understanding the Results

For many years, the legal standard for drunkenness across the United States was 0.10, but many states have now adopted the 0.08 standard. The federal government has pushed states to lower the legal limit. The American Medical Association says that a person can become impaired when the blood alcohol level hits 0.05. You should never drive an automobile when you are impaired by alcohol, drugs, or lack of proper rest.

Precautions

1. You should wait 20 minutes after eating or drinking before testing. Any alcohol remaining in the mouth or saliva takes this long to disperse and will interfere with the reading.
2. Avoid testing in a strong wind or in a closed room with dirty air.
3. When the "BATT LOW" LED is on, replace 9V alkaline battery.
4. Do not blow smoke or liquid into the unit. It will damage the sensor. Wait 1 minute after smoking before a test.
5. Although CA2000 analyzes alcohol level accurately, do not use it as a tool to drink and drive.
6. Store the unit between 32-104 (°F) and out of the reach of children.
7. Do not leave CA 2000 car adaptor hooked up to cigar jack.
8. In normal use, CA 2000 requires calibration every 12 months to obtain accurate results. Discuss with local distributors for calibration.

Troubleshooting

Replace the battery if the BATT LOW lamp comes on. Refer other problems to the toll free number below. No user serviceable components inside. Attempting to service the unit yourself voids the warranty.

Cleaning Instructions

For sanitation reasons, replace plastic mouthpiece if another person is going to use the unit.
You may wish to clean the unit with a damp cloth. Do not submerge in water. This will void the warrantee. No routine maintenance other than yearly calibration is required.

FINAL

Specifications

Dimensions:	4.7 x 2.4 x 1"	Weight	1.5 oz.
Battery:	9V alkaline	Operating Temp.	50 -104° F
Sensor:	Highly selective semi-conductor oxide sensor	Warm-up time	20 sec
Response time	5 sec	Accuracy	±0.01 % at 0.10% BAC
Calibration	BAC simulator	Calibration Interval	1 year

Warranty

We warrant the product to be free from defects in workmanship or material for 1 year in normal service from the date of purchase. Our duty under this warranty is limited to replacing, adjusting, or repairing the unit if returned along with proof of purchase. This warranty is void if unit has been tampered with or damaged by the user. Refer problems to the toll free number below.

Calibration:	Distributed by:
To recalibrate your alcohol tester, send it to this address: CA-2000 Calibration Center 12441 West 49th Ave/#4 Wheat Ridge, CO 80033 Please include a check or money order for $19.95 made payable to Lifeloc Technologies Inc. Your tester will be returned within 10 days.	KHN Solutions LLC 1136 Montgomery Street San Francisco, CA 94133 USA Phone: (415) 693-9756 Toll-Free 1-877-334-6876 Fax: (415) 693-0215 Email: info@breathalyzer.net Made in Korea

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 1 1 2004

KHN Solutions, LLC
c/o Mr. Daniel Kamm
Kamm and Associates
PO Box 7007
Deerfield, IL 60015

Re: k041334
Trade/Device Name: AlcoMate CA2000™ Digital Alcohol Detector
Regulation Number: 21 CFR 862.3050
Regulation Name: Breath-alcohol test system
Regulatory Class: Class I
Product Code: DJZ
Dated: May 18, 2004
Received: May 20, 2004

Dear Mr. Kamm

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

JUN 2 5 2004

Revised

Indications for Use

510(k) Number (if known): K041334

Device Name: AlcoMate CA2000™ Digital Alcohol Detector

Indications For Use: Intended to measure alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041334